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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,101	12/27/2005	Sarah C. Bodary-Winter	P1978R1	3802

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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,101	BODARY-WINTER ET AL.	
	Examiner	Art Unit	
	Padma V. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 18-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/9/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 10/23/08 is acknowledged and entered.

Status of Claims

2. Claims 13-17 are under examination.

The listing of claims indicate that claims 1-12 and 18-26 withdrawn, however , applicant in the remark section does not indicate that claims 1-12 and 18-26 are pending. Applicant indicates only claims 13-17 are pending. Applicant is requested to clarification the status of claims.

Claim Objections withdrawn

3. In view of amendment to the claim 13, the claim objection for non elected invention is with drawn.

Claim rejections -35 U.S.C. 101 withdrawn

4. In view of amendment to the claim 13, the rejection under 35 U.S.C. 101 is with drawn.

Claim rejections -35 U.S.C. 112 first withdrawn

5. In view of amendment to the claim 13, the rejections under 35 U.S.C. 112 are withdrawn

Information Disclosure Statement

6. The Information Disclosure Statement filed on 10/9/08 has been reviewed and a signed copy of the same is attached to this office action.

Specification objection maintained

7. Applicant did not respond to the specification objections made in the previous office action, therefore, the objections are maintained.

Claim Rejections - 35 USC § 102 maintained

8. The rejections of claims under 35 U.S.C. 102 (b) and 102(e) as being clearly anticipated by Ballinger et al and Haley et al Patent No. 6586390 respectively are maintained as set forth in the previous office action.

Applicant states 10/23/08 that claim 13 has been amended to recite an antibody which specifically binds to a polypeptide of SEQ ID NO:20, wherein said antibody reduces the severity of an immune-related disease associated with the over expression of PRO19600 . Ballinger *et al or* Haley do not disclose the association between the cited polypeptide and immune-related disease. Neither does this reference teach that PRO 19600 is over expressed in psoriasis.

The argument has been considered but has not been found persuasive because the claimed antibody disclosed by Ballinger et al has been used to treat chronic inflammations (e.g., asthma and arthritis) and immune disorders ,e.g., inflammatory reactions and autoimmune diseases. Therefore, it meets the limitation of the functional language. As the antibody used to treat the disease there is a relation between the treatment and antibody that binds to polypeptide. As Haley et al also teach the antibody that binds to a polypeptide of SEQ.ID.NO:20 can be used for the treatment of reducing immune coagulation of bacterial and viral diseases (see columns 5 and 6) , it reads on the functional language.

With respect to applicant's argument "Neither does this reference teach that PRO 19600 , SEQ.ID.NO:20 is over expressed in psoriasis" , the claim does not set forth the limitation which applicant is arguing about in the claim. Therefore, this rejection is maintained.

New Claim Objection /Rejections based on the amendment

Claim Objection

9. Claims 13 is objected for the recitation of "wherein said reduces" in line 2. The examiner understands that there is an oversight in omitting limitation "antibody" after said. Applicant is requested to amend the claim to recite "wherein said antibody reduces" in line 2.

Rejections 35 USC 112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 is rejected as being vague for the recitation of " PRO 19600" as the sole means of identifying the over expression of polypeptide. The use of laboratory designations to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. As such, the skilled artisan would not know the metes and bounds of the recited polypeptide. This rejection can be overcome by amending the claim to specifically and uniquely identify ing the polypeptide "PRO 19600", for example, by sequence identification number .

Rejections 35 USC 112,first paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (see MPEP 2163).

The claims are drawn to an isolated antibody which specifically binds to a polypeptide of SEQ ID NO:20, wherein said reduces the severity of an immune-related disease associated with the over expression of PRO19600, said antibody is a monoclonal antibody, a humanized antibody or a single-chain antibody. Claims are also drawn to a composition of matter comprising said antibody in combination with a carrier .

A review of the claim language recited in claim 13 indicates that it is drawn to a genus i.e., "an isolated antibody which specifically binds to a polypeptide of SEQ ID NO:20" embraces antibodies that bind to fragments/variants of SEQ ID NO:20 and thus read on diverse fragments/variants species. Thus, the scope of the claims includes a genus of "fragments/variants" antibodies and the genus is highly variant, inclusive to numerous structural variants because a significant number of structural differences between genus members is permitted. The specification teaches a single polypeptide as set forth as SEQ ID NO:20 and an isolated antibody which specifically binds to the polypeptide SEQ ID NO:20 . The specification does not place any structure, chemical or functional limitations on the antibodies that bind to fragments/variants of SEQ ID NO:20 embraced by claim .The recitation of "an isolated antibody which specifically binds to a polypeptide of SEQ ID NO:20 wherein said reduces the severity of an immune-related disease associated with the over expression of PRO19600" does not convey a common structure or function and is not so defined in the specification. Although the specification teaches that variants mean that SEQ ID NO:20 polypeptide wherein one or more amino acid

residues are added, or deleted, at the N- or C-terminus of the full-length native amino acid sequence and the claim do not provide any guidance on the structure of the polypeptide and what changes can or can not be made. For example, Lederman et al (Molecular Immunology 28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Li et al (Proc. Natl. Acad. Sci. USA 77:3211-3214, 1980) disclose that dissociation of immunoreactivity from other activities when constructing analogs (see entire document). Further, the specification does not teach either antibody that binds to SEQ.ID.NO: 20 is able to reduce any disease "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*.

Further, it is not sufficient to define it solely by its principal biological property, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. Per the *Enzo* court's example, (*Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CAFC 2002) at 1616) of a description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) couched "in terms of its function of lessening inflammation of tissues" which, the court stated, "fails to distinguish any steroid from others having the same activity or function" and the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity and which therefore, fails to satisfy the written description requirement. Similarly, the function of binding to the claimed antibodies does not distinguish a particular variant polypeptide from others having the same activity or function and as such, fails to satisfy the written-description requirement. Applicant has not disclosed any relevant, identifying characteristics, such as structure or other physical and/or chemical properties, sufficient to show possession of the claimed genus. Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required. A description of what a material does, rather than what it is, usually does not suffice. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Structural features that could distinguish a "fragment/variant " polypeptide in the genus from others in the protein class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. Since the disclosure does not describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of the binding of antibody alone is insufficient to describe the genus of antibodies that bind to fragment/ variant of SEQ ID NO:20 that function equivalently. However, in this case the function of the antibody as written is not set forth in the

specification. One of skill in the art would reasonable conclude that the disclosure of a single polypeptide, i.e., SEQ ID NO:20, does not provide a representative number of antibody species that bind to fragments/variants of SEQ ID NO:20 to describe the claimed genus and as a consequence antibodies that bind such. As such, generic antibodies that are unrelated via structure and function are highly variant and not conveyed by way of written description by the specification at the time of filing. As such the specification lacks written description for the highly variant genus of antibodies and one skilled in the art would not recognize that applicants had possession of the genus of claimed antibodies as instantly claimed.

Therefore, only isolated antibody which specifically binds to the polypeptide SEQ ID NO:20, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

14. Claims 13-17 are rejected under 36 U.S.C. 112, first paragraph, because the specification an isolated antibody which specifically binds to the polypeptide SEQ ID NO:20, said antibody is a monoclonal antibody, a humanized antibody or a single-chain antibody and a composition of matter comprising said antibody in combination with a carrier does not reasonably provide enablement for an antibody which specifically binds to a polypeptide of SEQ ID NO:20 , wherein said antibody reduces the severity of an immune-related disease associated with the over expression of PRO19600 said antibody is a monoclonal antibody, a humanized antibody or a single-chain antibody and a composition of matter comprising said antibody in combination with a carrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
Claims have been discussed supra.

Instant claims are evaluated for enablement using Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The present specification (pages 68-69) teaches that skin biopsies from lesional and non-lesional sites of psoriatic patients were taken in order to identify disease specific genes which are differentially expressed in psoriatic tissue. Genes were compared whose expression was up regulated in psoriatic skin vs. non-lesional skin thus comparing expression profiles of non-lesional skin and psoriatic skin from the

same patient, and also comparing against normal skin biopsies of normal healthy donors as a further control. The conclusion of these experiment indicated the polypeptide SEQ.ID.NO:20 (388 amino acid sequence) is expressed higher in psoriasis lesional skin than in matched non-lesional skin from psoriasis patients and normal skin taken from .subjects without psoriasis. However, the specification fails to teach a antibody which specifically binds to fragments /variants (i.e., a polypeptide) of SEQ ID NO:20.

One cannot extrapolate the teaching of the specification to the full enablement of the claims because the claims as written are broadly drawn to fragments /variants SEQ.ID.NO: 20 . The specification teaches a single polypeptide as set forth as SEQ ID NO:20. The specification does not place any structure, chemical or functional limitations on the variants embraced by claim .The recitation of " a polypeptide (i.e., fragments /variants) of SEQ.ID.NO:20 " does not convey a common structure or function and is not so defined in the specification. Although the specification teaches that variants mean that PRO polypeptides wherein one or more amino acid residues are added, or deleted, at the N- or C-terminus of the full-length native amino acid sequence and the claim do not provide any guidance on the structure of the polypeptide and what changes can or can not be made. For example, Lederman et al (Molecular Immunology 28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Li et al (Proc. Natl. Acad. Sci. USA 77:3211-3214, 1980) disclose that dissociation of immunoreactivity from other activities when constructing analogs (see entire document). As such the specification does not teach the highly variant genus of single function polypeptides (antibody binding). In view of the above, one of ordinary skill in the art would be forced into undue experimentation to practice the claimed invention.

Applicant 10/23/08 states that claim 13 has been amended to recite an antibody which specifically binds to a polypeptide of SEQ ID NO:20, wherein said antibody reduces the severity of an immune-related disease associated with the over expression of PRO19600 and the amended Claim 13 does not include the variant polypeptide of SEQ ID NO:20.

The argument has been considered but has not been found persuasive for the reasons set forth above in the instant rejection. Recitation of "a polypeptide of SEQ ID NO:20" in the claim reads on antibody binds to more than one polypeptide of SEQ ID NO:20 (i.e., fragment) , however, the current specification does not provide support for an isolated antibody that binds to fragments of SEQ.ID.NO:20 which reduces the severity of what immune-related disease.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956.

Respectfully,

/Padma v Baskar/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645